

REMARKSFormal Matters

Applicants note with appreciation that the Office has withdrawn the 35 U.S.C. § 103 rejections in view of the amendment filed with the response on December 1, 2008, and the Office has withdrawn the 35 U.S.C. § 112, first paragraph rejection in view of the arguments presented in the Office Action.

Response to Claim Rejections under 35 U.S.C. § 103

The Action rejects claims 1, 2, 4-8, 15, and 16 as allegedly being unpatentable over Troczynski et al. (U.S. Patent No. 6,426,114, hereinafter “Troczynski”) in view of Ito et al. (U.S. Patent Application 2005/0049715, hereinafter “Ito”). This rejection is respectfully traversed.

Applicants respectfully disagree with the Action’s determination regarding obviousness. Applicants submit that a *prima facie* case of obviousness has not been established, particularly because the Action has failed to show (1) that the combination of documents teaches or suggests every element of the claims, (2) a reason to modify the documents’ teachings to arrive at the claimed invention, and (3) a reasonable expectation of success in combining the teachings of the cited documents.

Cited documents fail to teach or suggest every element of the claimed invention

Applicants submit that Troczynski and Ito, alone or in combination, fail to teach or suggest all the elements of the present invention. In particular, Applicants submit that the cited documents do not teach or suggest, at least, “[a] porous calcium phosphate ceramic body comprising a substrate having fine pores, and three-dimensional nanotunnel layers having

pluralities of three-dimensionally connected nanotunnels formed on wall surfaces of said fine pores by mixing together calcium phosphate particles, a dispersant and water to form a slurry in a single dispersion state or near a single dispersion state, immersing said substrate in said slurry, and defoaming said slurry under reduced pressure, wherein said three-dimensional nanotunnel layers are formed in the fine pores inside the substrate.”

Applicants note that the present invention relates to the calcium phosphate nanotunnel layers which are three-dimensionally connected and are formed on wall surfaces of the fine pores of the calcium phosphate substrate. Applicants further note that the porous calcium phosphate ceramic body recited in the claim language is advantageous in accelerating the formation of new bone and obtaining a mechanical strength. As shown in paragraph [0023] and Figure 1 of the specification, the substrate of the nanotunnel layers are made of calcium phosphate and the nanotunnels are three-dimensionally connected. When the porous calcium phosphate ceramic body is embedded in a living body, the nanotunnels 21 in the three-dimensional nanotunnel layers 2 are filled with a body fluid. Bone-forming proteins are present in the body fluid, which are trapped in the nanotunnels 21. The undifferentiated mesenchymal cells, which generate osteoblasts, are attached to the surface of the porous calcium phosphate ceramic body or the fine pores 11, with the three-dimensional nanotunnel layers 2 as a scaffold, so that they are differentiated to osteoblasts in the fine pores 11. Further, the substrate and the nanotunnel layers have the same coefficient of thermal expansion, and the nanotunnel layers are unlikely to separate the substrate.

Accordingly, the porous calcium phosphate ceramic body of this invention has bone-forming proteins trapped in the nanotunnels 21, and the undifferentiated mesenchymal cells which are attached to the surface of the porous calcium phosphate ceramic body or the fine pores

11, with the three-dimensional nanotunnel layers 2 as a scaffold. As a result, the mesenchymal cells are differentiated to osteoblasts in the fine pores 11, leading to putting the osteoblasts in a state of easily forming bone, thereby accelerating the formation of bone around the porous calcium phosphate ceramic body (see paragraph [0023]). The porous calcium phosphate ceramic body of the present invention also has nanotunnel layers that are unlikely to separate from the substrate.

In contrast, Troczynski teaches a synthetic hydroxyapatite (HA) that exhibits strong affinity to host hard tissues (e.g. Ti alloy Dental implant) (column 1, lines 56-57) and disclose porous HA coatings deposited onto a Ti metal substrate, where pores were connected, ranging in size from 0.3 to 1 μm , which may be an advantage for the circulation of the physiological fluid throughout the coating (column 6, lines 56-57). Further, Troczynski discloses the porous HA coatings deposited onto a Ti metal substrate. However, Troczynski fails to teach a porous calcium phosphate ceramic body comprising the calcium phosphate substrate having fine pores, and the calcium phosphate nanotunnel layers on wall surfaces of the fine pores where nanotunnels are three-dimensionally connected. In an attempt to cure the deficiency of Troczynski, the Action relies on the teachings of Ito.

Applicants note that although Ito teaches an implant comprising porous calcium phosphate with a Ca/P molar ratio of 1.67, a porosity of 50% or more, and a pore size of 70 microns or more, Ito still fails to teach many elements of the present invention such as the nanotunnel layers, the nanotunnel layers being three-dimensionally connected, and the thickness of the nanotunnel layers.

Therefore, Applicants respectfully submit that none of the cited documents teaches all the elements of the present invention. Accordingly, the rejection on this basis should be withdrawn, which action is respectfully requested.

There is No Reason to Modify or Combine the Documents' Teachings

Applicants respectfully submit that there is no reason to modify or combine the teachings of Troczynski and Ito to arrive at the presently claimed invention. While the *KSR* court rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test in an obviousness inquiry, the Court acknowledged the importance of identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” in an obviousness determination. *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-1357 (Fed. Cir. 2007) (quoting *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007)).

Applicants further submit that the motivation stated by the Office for combining the cited documents would not have prompted a person of ordinary skill in the relevant field to combine the elements in the way the present invention does. Further, there is nothing in any of the documents to suggest to the ordinary skilled person to modify or combine the documents’ teachings.

The Action states that the reason for combining Troczynski with Ito is the “desire to facilitate osteogenesis activity while maintaining the strength of the implant” (Office Action, page 3). Applicants respectfully submit the Action’s stated rationale for combining the references does not motivate or otherwise provide a reason for a person skilled in the art to combine Troczynski and Ito. In particular, Ito discloses an implant comprising a porous

substrate of calcium phosphate; and it is noted that generally, calcium phosphate coatings are not formed on calcium phosphate substrates. This is because there is no significant effect when common calcium phosphate coatings are simply formed on calcium phosphate substrates.

Applicants note that the current invention is obtained when calcium phosphate nanotunnel layers, where the nanotunnels are three-dimensionally connected, are formed on calcium phosphate substrates having fine pores. Applicants therefore submit that the stated motivation to combine the cited references is not sufficient and would not prompt one skilled in the art to combine the teachings of the cited art to arrive at the present invention

Applicants further note that Troczynski teaches the effect of porous HA coatings is the circulation of the physiological fluid throughout the coating structure, which is different from the effect of the present invention. Therefore, Applicants submit that one skilled in the art would not be motivated to make this invention by applying the porous HA coatings of Troczynski to the porous substrate of calcium phosphate of Ito.

No Reasonable Expectation of Success in Combining the Cited Documents

Applicants submit that there is no reasonable expectation of success in combining the cited documents. Applicants note that the Action failed to show or even state that there would be a reasonable expectation of success when Troczynski and Ito are combined.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established, particularly because the Office failed to show (1) that the combination of documents teaches or suggests every element of the claims, (2) a reason to modify the documents' teachings to arrive at the claimed invention, and (3) a reasonable expectation of success in combining the teachings of the cited documents.

The Action also rejects claims 1, 2, 4-8, 15, and 16 as allegedly being unpatentable over Troczynski et al. (U.S. Patent No. 6,426,114) in view of Ito et al. (U.S. Patent Application 2005/0049715), and further in view of Ahn (U.S. Patent Application 2005/0031704). This rejection is also respectfully traversed.

Applicants respectfully disagree with the Action's determination regarding obviousness. Applicants submit that a *prima facie* case of obviousness has not been established, particularly because the Office failed to show (1) that the combination of documents teaches or suggests every element of the claims and (2) a reason to modify the documents' teachings to arrive at the claimed invention.

Cited documents fail to teach or suggest every element of the claimed invention

Applicants submit that Troczynski, Ito, and Ahn, alone or in combination, fail to teach or suggest all the elements of the present invention. In particular, Applicants submit that the cited documents do not teach or suggest, at least, "[a] porous calcium phosphate ceramic body comprising a substrate having fine pores, and three-dimensional nanotunnel layers having pluralities of three-dimensionally connected nanotunnels formed on wall surfaces of said fine pores by mixing together calcium phosphate particles, a dispersant and water to form a slurry in a single dispersion state or near a single dispersion state, immersing said substrate in said slurry, and defoaming said slurry under reduced pressure, wherein said three-dimensional nanotunnel layers are formed in the fine pores inside the substrate."

Applicants note that the Action employs Ahn to supplement the teachings of Troczynski and Ito. Applicants note that the arguments presented above with regard to Troczynski and Ito, are applicable to this section and are incorporated by reference herein. In contrast to the

teachings of the present invention, Ahn teaches a calcium phosphate composition that serves as a coating for prosthetic implants where the coating is porous and includes a non-ionic surfactant as an organic additive. However, Ahn still fails to teach the nanotunnel layers, the nanotunnel layers being three-dimensionally connected, the thickness of the nanotunnel layers, and several other elements of the claimed invention.

Applicants note that none of the cited documents teaches all the elements of the present invention. In addition, even assuming *arguendo*, that Troczynski, Ito, and Ahn are combinable, all the elements of the present invention are still not taught or suggested.

There is No Reason to Modify or combine the Documents Teachings

Applicants respectfully submit that there is no reason to modify or combine the teachings of Troczynski, Ito, and Ahn to arrive at the presently claimed invention. Applicants further submit that the reason stated by the Office for combining the cited documents would not have prompted a person of ordinary skill in the relevant field to combine the elements in the way the present invention does, in contrast to the requirement of the *KSR* court. (see *KSR*, 127 S.Ct. 1727,1731 (2007)). Further, there is nothing in any of the documents to suggest to the ordinary skilled person to modify or combine the documents' teachings.

Applicants initially note that the arguments presented regarding the lack of adequate motivation to combine the teachings of Troczynski and Ito, are applicable with regard to the arguments of this section. Specifically, if there is a lack of motivation to combine Troczynski, Ito, then there is no reason to combine Troczynski, Ito, and Ahn.

No Reasonable Expectation of Success in Combining the Cited Documents

Applicants submit that there is no reasonable expectation of success in combining the cited documents. Applicants note that the Action failed to show or even state that there would be a reasonable expectation of success when Troczynski, Ito, and/or Ahn are combined.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established, particularly because the Office failed to show (1) that the combination of documents teaches or suggests every element of the claims and (2) a reason to modify the documents' teachings to arrive at the claimed invention.

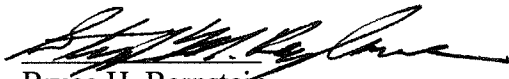
With respect to the obviousness rejection addressing product-by-process claims, Applicants note that the question is whether the *process* limitations result in a materially different *product*. Applicants respectfully disagree with the Action's determination that the product of the presently claimed invention is the same as or obvious from the product taught by Troczynski, Ito, and Ahn. In this regard, Applicants note, as argued above, that the presently claimed invention differs from the products disclosed in Troczynski, Ito, and Ahn, specifically because the cited references do not teach or suggest, at least, "[a] porous calcium phosphate ceramic body comprising a substrate having fine pores, and three-dimensional nanotunnel layers having pluralities of three-dimensionally connected nanotunnels formed on wall surfaces of said fine pores by mixing together calcium phosphate particles, a dispersant and water to form a slurry in a single dispersion state or near a single dispersion state, immersing said substrate in said slurry, and defoaming said slurry under reduced pressure, wherein said three-dimensional nanotunnel layers are formed in the fine pores inside the substrate." Accordingly, the Action's conclusion that the product-by-process claims is unpatentable is erroneous and the rejection should be withdrawn.

In view of the foregoing, Applicants respectfully request withdrawal of the outstanding rejections of claims 1, 2, 4-8, 15 and 16 under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the rejections of record, and allow all the pending claims.

Respectfully Submitted,
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